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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,065	02/08/2005	Takaya Sugawara	KPO-TSC-P1/TK-80/US	4447

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EXAMINER	
ELLIS, SUEZU Y	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,065	SUGAWARA ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/13/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 13, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akemi et al. (US 5,242,951).

With respect to claims 1 and 2, Akemi et al. discloses an external patch comprising a backing (substrate) and a pressure-sensitive adhesive layer, wherein the pressure-sensitive adhesive layer is made of an acrylic pressure-sensitive adhesive

(crosslinked gel layer having acrylate polymer) containing an isocyanate-based crosslinking agent and containing 0.5 to 10% by weight of a female hormone (estradiol) as an active ingredient (col. 2, lines 30-65; col. 3, lines 30-48; col. 5, lines 17-20, 33-35, 40-52). The adhesive is considered to be pressure-sensitive since it is made of the same material as that of the applicant. Akemi et al. fails to expressly disclose the isocyanate-based crosslinking agent being 0.01-1% by weight, however does teach using isocyanate-based crosslinking agent used in an amount from 0.01 to 2.0 parts by weight per 100 parts by weight of acrylate polymer (col. 5, lines 33-35). It would have been obvious to one of ordinary skill in the art to modify the amount of isocyanate-based crosslinking agent since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Akemi et al. in view of Yamaguchi et al. (US 5,820,877).

With respect to claim 3, Akemi et al. discloses an external patch comprising a backing (substrate) and a pressure-sensitive adhesive layer, wherein the pressure-sensitive adhesive layer is made of an acrylic pressure-sensitive adhesive (crosslinked gel layer having acrylate polymer) containing an isocyanate-based crosslinking agent and containing 0.5 to 10% by weight of a female hormone (estradiol) as an active ingredient, and oleic acid (col. 2, lines 30-65; col. 3, lines 30-48; col. 5, lines 17-20, 33-35, 40-52; col. 4, lines 34-44). The adhesive is considered to be pressure-sensitive

since it is made of the same material as that of the applicant. Akemi et al. fails to expressly disclose the isocyanate-based crosslinking agent being 0.01-1% by weight and the oleic acid being 0.1-10% by weight, however does teach using isocyanate-based crosslinking agent used in an amount from 0.01 to 2.0 parts by weight per 100 parts by weight of acrylate polymer and using various ranges of oleic acid (col. 4, lines 50-55; col. 5, lines 33-35). It would have been obvious to one of ordinary skill in the art to modify the amount of isocyanate-based crosslinking agent and oleic acid since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. The modified Akemi et al. also fails to expressly disclose the inclusion of crotamiton and the quantity used. Yamaguchi et al. discloses a patch comprising estradiol, oleic acid and crotamiton (col. 4, lines 1-2, 38-54). It would have been obvious to one of ordinary skill in the art to include crotamiton in order to solubilize the drug, as desired. It also would have been obvious to one of ordinary skill in the art to modify the quantity of crotamiton used in order to provide a patch that therapeutically effective and pharmacologically acceptable, as taught by Yamaguchi et al. (col. 4, lines 54-58).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (US 5,693,335) in view of Hoffmann et al. (US 5,393,529).

With respect to claim 4, Xia et al. discloses an external patch comprising a backing and a pressure-sensitive adhesive layer, wherein the pressure-sensitive

adhesive layer is made of an acrylic pressure-sensitive adhesive containing a crosslinking agent, isoproyl myristate as a distribution coefficient control agent (skin permeation enhancer) and norethindrone (equivalent to noresthisterone) as an active ingredient (col. 2, lines 17-27, 34-59; col. 3, lines 39-50). The adhesive is considered to be pressure-sensitive since it is made of the same material as that of the applicant. Xia et al. discloses examples of the crosslinking agents used are in Hoffman et al. Hoffman et al. discloses norethisterone-containing transdermal systems utilizing isocyanate-based crosslinking agents (col. 3, lines 43-54; col. 5, line 55). Although Xia et al. and Hoffman et al. fail to expressly disclose the same exact quantity range for each ingredient as claimed, Xia et al. and Hoffman et al. teach using various quantity ranges for each ingredient (e.g. Xia et al. teaches in col. 2, lines 25-27, the norethindrone being 0.2-6% by weight and Hoffman discloses in col. 2, lines 59-63, the norethisterone being 0.5-10% by weight). It would have been obvious to one of ordinary skill in the art to modify the quantity for each ingredient in order to optimize the desired medicinal benefits. Further, it has been held that discovering an optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 1/5 and 2/5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akemi et al. in view of Xia et al.

With respect to claims 1/5 and 2/5, the modified Akemi et al. addresses all the limitations of claims 1 and 2, and further discloses the backing is a laminate structure comprising a nonporous sheet (polyester film) having a thickness of 0.1-10 μm and a

flexible polymer film and a woven or nonwoven fabric having a thickness of 1-200 μm (col. 2, lines 30-65). The modified Akemi et al. fails to expressly disclose the polyester film being polyethylene terephthalate. Xia et al. discloses a transdermal path comprising estradiol and the patch having a backing comprising polyethylene terephthalate (col. 3, lines 39-50). It would have been obvious design choice to one of ordinary skill in the art to modify the material of the backing to be polyethylene terephthalate for the predictable result of providing a backing layer having the properties of strength and flexibility as a support and of impermeability to the drug.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

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